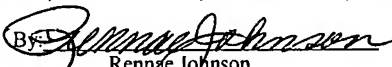


SERIAL NO. 10/625,826

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Appellant: Wagner et al. Examiner: Prone, C.
Serial No.: 10/625,826 Group Art Unit: 3738
Filing Date: July 23, 2003 Docket No.: GUID.619PA
(03-521)
Title: TUNNELING TOOL WITH SUBCUTANEOUS TRANSDERMAL ILLUMINATION

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Mail Stop Appeal Brief - Patents, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450, on November 1, 2006.

By: 
Renne Johnson

APPEAL BRIEF

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Sir:

This Appeal Brief is submitted pursuant to 37 C.F.R. §41.37 for the above-referenced patent application consistent with the Notice of Appeal filed on July 10, 2006, and the Panel Decision from Pre-Appeal Brief Review to proceed to the Board of Patent Appeals and Interferences dated September 5, 2006.

Please charge deposit account 50-3581 (GUID.619PA) in the amount of \$500.00 for filing this brief in support of an appeal by a large-entity as set forth in 37 C.F.R. §41.20(b)(2). If necessary, authority is given to charge/credit deposit account 50-3581 (GUID.619PA) additional fees/overages in support of this filing.

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I. REAL PARTY IN INTEREST

The real party in interest is the assignee, Cardiac Pacemakers, Inc.



II. RELATED APPEALS AND INTERFERENCES

Appellant is unaware of any related appeals, interferences or judicial proceedings that would have a bearing on the Board's decision in the instant appeal.

III. STATUS OF CLAIMS

Claims 1-5, 8-11, 44, 46, 47, 49, 50, 53-58 and 61-63 are pending, each of which is presented for appeal. Each of the pending Claims 1-5, 8-11, 44, 46, 47, 49, 50, 53-58 and 61-63 has been finally rejected by the Examiner's action dated March 9, 2006, from which Appellant appeals.

The pending Claims 1-5, 8-11, 44, 46, 47, 49, 50, 53-58 and 61-63 under appeal may be found in the attached Claims Appendix.

IV. STATUS OF AMENDMENTS

No amendments have been presented subsequent to the final rejection dated March 9, 2006.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The present invention is directed to a subcutaneous dissection tool for deploying subcutaneous cardiac devices, therapies, and combinations thereof, and that is capable of transdermal illumination during dissection. As the light emanates from the tool through a patient's tissue and skin, a clinician may use the tool to identify the location of the tool along the dissection path and/or the depth of the tool. The illumination is used as a visual aid to identify the location of the tool for improved navigation and placement of subcutaneous leads.

One embodiment of the present invention is directed to a dissection tool. *See, e.g.*, Claim 1; Figs. 2, 5A-B, and 6A-C; and the corresponding discussion in the Specification at page 11, line 12 through page 12, line 26, and page 14, line 12 through page 16, line 21. The dissection tool (*e.g.*, 290) includes a handle (*e.g.*, 260) having a proximal end and a distal end and an elongated dissecting member (*e.g.*, 280) having a proximal end and a distal end. The elongated dissecting member extends from the distal end of the handle, and a light source (*e.g.*, 282) is provided at the distal end of the dissecting member. The light source is adapted to provide a visible locating reference through the skin.

Other embodiments may be directed to a dissection tool having a handle and an elongated dissecting member as discussed above, as well as means for illuminating a path of subcutaneous tissue dissection. *See, e.g.*, Claim 44; Figs. 2, 4A-B, and 5B; and the corresponding discussion in the instant Specification at page 11, line 12 through page 12, line 26, page 13, line 23 through page 14, line 11, and page 14, line 16 through page 15, line 5. The means for illuminating a path of subcutaneous tissue dissection (*e.g.*, 282) may include, for example, a light source such as an incandescent bulb, a light emitting diode (LED), a fluorescent light source, a vapor lamp, an arc lamp, a plasma light source, and a halogen bulb. The means for illuminating a path may also include a switch (*e.g.*, 275) such as a pull-tab, a physical switch, or a computer controlled switch including a voice-activated relay. Various power sources (*e.g.*, 272) may also be included in the means for illuminating a path such as a storage battery, a fuel cell, a rechargeable battery, an electrochemical cell. Both a switch and power source may be located within the dissection tool or located external to the tool. The means for illuminating a path may also include light filters and a light pipe (*e.g.*, 550).

Another embodiment of the present invention is directed to a dissection tool. *See, e.g.*, Claim 53; Fig. 2; and the corresponding discussion in the Specification at page 11, line 12

through page 12, line 26. The dissection tool (*e.g.*, 290) includes a handle (*e.g.*, 260) having a proximal end and a distal end and an elongated dissecting member (*e.g.*, 280) having a proximal end and a distal end. The elongated dissecting member extends from the distal end of the handle and includes at least one curved portion (*e.g.*, 280). An optical location indicator (*e.g.*, 282) is provided at the distal end of the dissecting member and is adapted to provide a visible indication of the distal end of the dissecting member through the dermis.

As required by 37 C.F.R. § 41.37(c)(1)(v), a concise explanation of the subject matter defined in each of the independent claims involved in the appeal is provided herein. Appellant notes that representative subject matter is identified for each of these claims; however, the abundance of supporting subject matter in the application prohibits identifying all textual and diagrammatic references to each claimed recitation. Appellant thus submits that other application subject matter, which supports the claims but is not specifically identified above, may be found elsewhere in the application. Appellant further notes that this summary does not provide an exhaustive or exclusive view of the present subject matter, and Appellant refers to the appended claims and their legal equivalents for a complete statement of the invention.

VI. GROUND OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1-5, 8-11, 44, 46, 47, 49, 50, 53-58 and 61-63 stand rejected under 35 U.S.C. §102(b) based on Chen *et al.* (U.S. Pat. No. 5,445,608).

VII. ARGUMENT

The rejection under 35 U.S.C. §102(b) is improper because Chen *et al.* fails to correspond to each of the limitations of the claimed invention.

Each of independent Claims 1, 44 and 53 include limitations directed to an elongated dissecting member included in a dissection tool. Appellant maintains that U.S. Patent No. 5,445,608 to Chen *et al.* (hereinafter “Chen”) does not teach limitations directed to a dissecting member, as claimed.

In attempting to assert correspondence to Appellant’s claimed elongated dissecting member, the Examiner relies upon Chen’s flexible catheter 262. However, the Examiner has not identified where Chen teaches that flexible catheter 262 is a dissecting member, as claimed. In the Advisory Action dated June 8, 2006, the Examiner merely asserts that Chen “is fully capable of dissecting tissue” without providing any evidence in support of such an assertion. Moreover, Appellant fails to recognize any such evidence in the teachings of Chen. Without a presentation of evidence that Chen corresponds to each of the claimed limitations, the Examiner has not shown that the teachings of Chen satisfy the requirements for a §102(b) rejection.

To anticipate a claim, the reference must teach every element of the claim. “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the patent claim; *i.e.* every element of the claimed invention must be literally present, arranged as in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Therefore, all claim elements, and their limitations, must be found in the prior art reference to maintain the rejection based on 35 U.S.C. §102. Appellant respectfully submits that Chen does not teach every element of independent Claims 1, 44 and 53 in the requisite detail, and therefore fails to anticipate Claims 1-5, 8-11, 44, 46, 47, 49, 50, 53-58 and 61-63.

Chen’s flexible catheter cannot correspond to the claimed elongated dissecting member as evidenced by the teachings of Chen. First, the flexible catheters taught by Chen could not be dissecting members as their flexibility prevents them from sustaining axial loads required to

dissect body tissue. For example, Chen teaches that flexible catheter 176 is made of PMMA or silicone rubber material so as to form a 360 degree loop. *See, e.g.*, Fig. 12A and column 20, lines 13-15.

Second, Chen's implantable probe (to which the flexible catheter is coupled) is positioned at a treatment site only after access to the site is made possible by a surgical procedure that must be performed prior to implantation of the probe. For example, and with reference to column 8, lines 6-13, Chen teaches that one such surgical procedure involves making an incision that allows insertion of the implantable probe into the cardiovascular system. At column 24, lines 33-37, *Chen* teaches that a skin penetration procedure, perhaps requiring minor surgery, "is necessary to introduce and position the implantable probe at the treatment site" (*emphasis added*). Further, Chen teaches that a flexible catheter (such as catheter 262) is placed in a patient using a guide wire. *See, e.g.*, column 23, lines 45-47 and column 24, lines 1-3. Thus, Chen's flexible catheter is not used for dissection, but rather, access must be created by another instrument that is suitable for penetrating the skin and underlying tissue.

No evidence has been shown that Chen's flexible catheter is a dissecting member, as claimed, and Chen's teachings contradict any assertion that the flexible catheter would correspond to the claimed limitations. Moreover, the Chen reference does not include the term "dissect." The teachings of Chen are insufficient to support the §102(b) rejection because the disclosure in an anticipating reference must provide an enabling disclosure of the desired subject matter; mere naming or description of the subject matter is insufficient, if it cannot be produced without undue experimentation. *Elan Pharm., Inc. v. Mayo Foundation for Medical and Education Research*, 346 F.3d 1051, 1054 (Fed. Cir. 2003). *See, also*, MPEP §2121.01. As discussed above, Chen does not name or describe a dissecting member, and it is unclear how a skilled artisan could arrive at the claimed structure using Chen's teachings without undue experimentation. For at least the reasons set forth above, Chen's description of an implantable probe connected to (or passed through) a flexible catheter fails to support the §102(b) rejection. Appellant accordingly requests that the rejection be reversed.

Regarding the Examiner's assertion that "Appellant is simply arguing about intended use of the invention," Appellant respectfully traverses. Each of the independent claims is directed to a dissection tool including a dissecting member. Appellant notes that "[A]pparatus

claims cover what a device *is*, not what a device *does*.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original). *See*, also, MPEP §2114. The recitation of “an elongated dissecting member” is a structural limitation that must be considered for the claims to be examined in their entirety. Appellant’s arguments with respect to the failure of Chen to teach a dissecting member, as claimed, are based upon Chen’s failure to correspond to the structure of the claimed invention and not merely “intended use.”

With particular respect to the rejection of independent Claims 1 and 53, since Chen fails to disclose a dissecting member extending from a handle, Chen also fails to teach a light source or an optical location indicator provided at the distal end of a dissecting member. Further, the Examiner has not asserted or shown that Chen’s light sources are adapted to provide a visible locating reference through the skin or dermis, as claimed.

The recitation of a light source adapted to provide a visible locating reference through the skin or dermis is a structural feature that must be considered. Defining structures in terms of interrelationships or attributes they must possess has been long sanctioned in the case law. For example, *In re Venezia*, 530 F.2d 956, 959 (CCPA 1976), clarified that language such as “adapted to be affixed” and “adapted to be positioned” defines structures or attributes of the element in question and limits the element to those configurations which allow for the stated interrelation of the element with other structures. *Id.* The Examiner has not shown that Chen’s light sources, infrared or LED, provide a visible locating reference through the skin. Since Chen teaches that the light source is activated after the light source is placed at a treatment site within the patient to provide local irradiation of tissue at the treatment site, the location of the light source (or probe) is already known. *See, e.g.*, column 11, lines 46-55. Thus, Appellant fails to recognize how Chen’s light source would be used to provide a visible locating reference, as claimed.

If by stating that Chen teaches using LEDs as a light source, the Examiner is asserting that Chen inherently teaches a light source adapted to provide a visible locating reference through the skin or dermis, Appellant respectfully traverses such assertion. The Examiner has not presented any of the requisite evidence for supporting an assertion of inherency. Appellant notes that “The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d

1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art). MPEP §2112 further states that “To establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.’ *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999).” As discussed above, the light source is not activated until the probe is in place and the location of the probe is already known. Thus, a visible locating reference would no longer be needed. The Examiner has not provided any evidence that Chen teaches a light source adapted to provide a visible locating reference through the skin or dermis, as claimed. Thus, Chen does not teach each of the claimed limitations, and the limitations have not been shown to be inherent.

Dependent Claims 2-5, 8-11, 46, 47, 49, 50, 54-58 and 61-63 depend from independent Claims 1, 44 and 53, respectively and also stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Chen. While Appellant does not acquiesce with the particular rejections to these dependent claims, these rejections are also improper for the reasons discussed above in connection with independent Claims 1, 44 and 53. These dependent claims include all of the limitations of their respective base claims and any intervening claims and recite additional features which further distinguish these claims from the cited reference. Therefore, the rejection of dependent Claims 2-5, 8-11, 46, 47, 49, 50, 54-58 and 61-63 is improper.

Appellant respectfully submits that Chen does not teach each of the claimed limitations and therefore fails to support the §102(b) rejection. Chen at least fails to teach an elongated dissecting member extending from the distal end of a handle and a light source provided at the distal end of a dissecting member. Chen does not teach an apparatus that corresponds to the claimed invention in the requisite detail. *See, Richardson v. Suzuki Motor Co.* For at least these reasons, Appellant requests that the rejection be reversed.

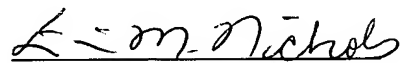
VIII. CONCLUSION

In view of the above, Appellant respectfully submits that the claimed invention is patentable over the cited reference and that the rejection of claims 1-5, 8-11, 44, 46, 47, 49, 50, 53-58 and 61-63 should be reversed. Appellant respectfully requests reversal of the rejection as applied to the appealed claims and allowance of the entire application.

Authorization to charge the undersigned's deposit account is provided on the cover page of this brief.

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Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Erin M. Nichols", written in black ink.

Name: Erin M. Nichols
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IX. CLAIMS APPENDIX

1. A dissection tool, comprising:
 - a handle having a proximal end and a distal end;
 - an elongated dissecting member having a proximal end and a distal end, the elongated dissecting member extending from the distal end of the handle; and
 - a light source provided at the distal end of the dissecting member, the light source adapted to provide a visible locating reference through the skin.
2. The dissection tool of claim 1, further comprising a battery adapted to provide power to the light source.
3. The dissection tool of claim 1, further comprising a power line having a distal end extending from the light source and a proximal end extending to at least a surface of the handle, the proximal end of the power line coupled to a connector adapted to matingly engage a connector of an external power source.
4. The dissection tool of claim 1, further comprising a switch provided on the handle of the dissection tool, wherein the switch is adapted to toggle the light source off and on.
5. The dissection tool of claim 1, wherein the light source comprises a light emitting diode.
8. The dissecting tool of claim 1, further comprising a fluid channel system extending from the proximal end of the elongated dissecting member to the distal end of the elongated dissecting member, the fluid channel system terminating in a port system.
9. The dissecting tool of claim 8, wherein the fluid channel system is adapted to transport a pharmacological agent.

10. The dissecting tool of claim 9, wherein the pharmacological agent comprises one or more of an analgesic, an antibiotic, and an antiseptic agent.

11. The dissecting tool of claim 8, wherein a first fluid channel is adapted to transport irrigation fluid and a second fluid channel is adapted to transport a pharmacological agent.

44. A dissection tool, comprising:
a handle having a proximal end and a distal end;
an elongated dissecting member extending from the distal end of the handle; and
means for illuminating a path of subcutaneous tissue dissection.

46. The dissection tool of claim 44, further comprising means for providing internal power to the illuminating means.

47. The dissection tool of claim 44, further comprising means for switching the illuminating means between off and on states.

49. The dissection tool of claim 44, further comprising means for coupling light from an internal light source to the illuminating means.

50. The dissection tool of claim 44, wherein the illuminating means comprises a light emitting diode.

53. A dissection tool, comprising:
a handle having a proximal end and a distal end;
an elongated dissecting member extending from the distal end of the handle, the dissecting member having a proximal end, a distal end, and at least one curved portion; and
an optical location indicator provided at the distal end of the dissecting member and adapted to provide a visual indication of a location of the distal end of the dissecting member through the dermus.

54. The dissection tool of claim 53, wherein the elongated dissecting member has a curvature appropriate for dissection along a plane that follows a curvature of a rib-cage.

55. The dissection tool of claim 53, wherein the elongated dissecting member has a generally arcuate shape.

56. The dissection tool of claim 53, further comprising means for providing power to the optical location indicator.

57. The dissection tool of claim 53, further comprising means for switching the optical location indicator between off and on states.

58. The dissection tool of claim 53, wherein the optical location indicator comprises a light emitting diode.

61. The dissection tool of claim 53, further comprising a fluid channel system extending between the proximal and distal ends of the dissecting member, the fluid channel system terminating in a port system.

62. The dissection tool of claim 61, wherein the fluid channel system is adapted to transport a pharmacological agent.

63. The dissection tool of claim 62, wherein the pharmacological agent comprises one or more of an analgesic, an antibiotic, and an antiseptic agent.

X. EVIDENCE APPENDIX

None.

XI. RELATED PROCEEDINGS APPENDIX

None.